

SEP 21 2004
510(K) SUMMARY

510(k) Number K K041805

Applicant's Name:

Miras Mirror Imaging Solutions Ltd.
31 Habarzel St.
Tel Aviv, 69710 Israel
Tel.: 972-3-6442595
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Contact Person:

Dorit Winitz Ph.D
Biomedical Strategy Ltd.
11 Menachem Begin Street.
Ramat Gan 52521, Israel
Tel: 972-3- 6123281
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Date Prepared:

June 2004

Trade Name:

MirroScope™ System

Classification Name:

UNIT, OPERATIVE DENTAL
Product Code:
Regulation No:
Class: I
Panel: Dental

Classification:

Product Code: EIA
Regulation No: 872.6640
Class: I
Panel: Dental

Predicate Device:

- The AcuCam Concept IV Intraoral Camera System (Dentsply International, Inc.), cleared under K000112
- The Cdr-Cam System (Schick Technologies, Inc.), cleared under K963778
- The FlexiScope Optomodul (Schoelly Fiberoptic, GmbH), cleared under K984641
- Class I Exempt Dental Mirror (product code EAX)

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the MirroScope™ System complies with the following voluntary standards:

- IEC 60601-1(1988)+A1(1991)+A2(1995)
- IEC/EN 60601-1-2 (2001)
- CAN/CSA-C22.2 No. 601.1.2-94(R1999); CISPR 11(2003) group 1 class B
- IEC 60601-1-4 (1999)
- EN 1441 (1997)
- ISO 14971 (2000)

Intended Use / Indication for Use:

The MirroScope™ System is indicated for use during dental examinations and procedures when a video image is desired.

Device Description:

The MirroScope™ System is an intraoral camera that is mounted on a customary mirror and complimentary imaging accessories.

The System consists of the following main components:

1. The MirroScope™

The MirroScope™ is a handpiece comprised of a mirror (MirroLens), alignment of prisms and lenses, a miniature 1/4" CCD camera Remote Head Unit (RHU), located in the handle. The video signal from the RHU is transferred to the Camera Control Unit (CCU) located in a control box, via a lightweight cable. A set of six LED's illuminates the working area around the mirror. A disposable, single use protective sheath is provided to be mounted over the handpiece prior to each use, to ensure proper hygiene and to serve as a barrier cover.

2. Two complementary packages, the PRO-200™ and the VIEW-300™, to provide either an overall solution or an add-on solution to the existing infrastructure:

The PRO-200™ includes the following:

- Control Box:
 - Camera Control Unit (CCU)
 - Video Processing Unit (VPU)
 - Power Supply Unit (PSU)
 - RF Transmitter (Optional)
 - Infrared Receiver (IRR)
 - Docking station for MirroScope™
- R-400 Infrared remote control
- External AC/DC adaptor
- Foot pedal (Optional)
- RF Receiver (Optional)

The VIEW-300™ includes the following:

- Control box:
 - Camera Control Unit (CCU)
 - Video Processing Unit (VPU)
 - Power Supply Unit (PSU)
 - 12.1" TFT screen and Converter
 - Infrared Receiver (IRR)
 - Docking station for MirroScope™
- R-400 Infrared remote control
- External AC/DC adaptor
- Accessories:
- Foot pedal (Optional)

Substantial Equivalence:

The MirroScope™ System and its predicate devices share the same intended use and similar materials and design. A comprehensive testing program was developed and performed in order to verify that the MirroScop™ System does not raise any new safety and effectiveness issues in comparison to its predicate device. This includes the following testing and activities:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-2 standards.
- Software verification and validation testing
- Performance testing
- Effective clinical images and use evaluation

- Hazard analysis including risk level and solutions performed in compliance with AAMI/ISO 14971-1, 2000 is attached

Altogether, Miras Mirror Imaging Solutions Ltd. believes that the MirroScope™ System is safe and effective for its intended use and is substantially equivalent to its predicate devices cited above without raising any new safety and/or effectiveness issue.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 21 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Miras Mirror Imaging Solutions, Limited
C/O Dr. Dorit Winitz
Company Consultant
Biomedical Strategy Limited
11 Menachem Begin Street
Ramat Gan 52521,
ISRAEL

Re: K041805
Trade/Device Name: The MirroScope™ System
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: June 20, 2004
Received: July 6, 2004

Dear Dr. Winitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

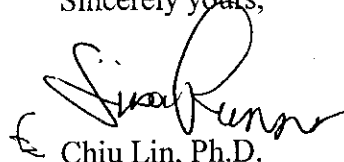
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041805

Device Name: The MirroScope™ System

Indications for Use: The MirroScope™ System is indicated for use during dental examinations and procedures when a video image is desired.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number _____

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over the Counter
Use _____

Susan R. [Signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041805